§ 640.31 Suitability of donors.

(a) Whole blood donors shall meet the criteria for donor suitability prescribed in § 640.3.

(b) Plasmapheresis donors shall meet the criteria for donor suitability prescribed in § 640.63, excluding the phrase ''other than malaria'' in paragraph (c)(9) of that section. Informed consent shall be required as prescribed in § 640.61.

(c) Donors shall not be suitable if they are known to have been immunized within the past 6 months by injection with human red blood cells.

[42 FR 59878, Nov. 22, 1977]

§ 640.32 Collection of source material.

(a) Whole blood shall be collected, transported, and stored as prescribed in § 640.4, except that paragraphs (d)(2) and (h) of that section shall not apply. When whole blood is intended for Plasma, Fresh Frozen Plasma, and Liquid Plasma, it shall be maintained at a temperature between 1 and 6 °C until the plasma is removed. Whole blood intended for Platelet Rich Plasma, shall be maintained as prescribed in § 640.24 until the plasma is removed. The red blood cells shall be placed in storage at a temperature between 1 and 6 °C immediately after the plasma is separated.

(b) Plasma obtained by plasmapheresis shall be collected as prescribed in §§ 640.62, 640.64 (except that paragraph (c)(3) of § 640.64 shall not apply), and § 640.65.

[42 FR 59878, Nov. 22, 1977, as amended at 45 FR 27927, Apr. 25, 1980; 50 FR 4139, Jan. 29, 1985]

§ 640.33 Testing the blood.

(a) Blood from which plasma is separated shall be tested as prescribed in §§ 610.40 and 610.45 of this chapter and § 640.5 (a), (b), and (c).

(b) Manufacturers of Plasma collected by plasmapheresis shall have testing and recordkeeping responsibilities equivalent to those prescribed in §§ 640.71 and 640.72.

[42 FR 59878, Nov. 22, 1977, as amended at 44 FR 17658, Mar. 23, 1979; 50 FR 4139, Jan. 29, 1985; 53 FR 117, Jan. 5, 1988]

§ 640.34 Processing.

(a) *Plasma.* Plasma shall be separated from the red blood cells within 26 days after phlebotomy (within 40 days after phlebotomy when CPDA–1 solution is used as the anticoagulant), and shall be stored at −18 °C or colder within 6 hours after transfer to the final container, unless the product is to be stored as Liquid Plasma .

(b) *Fresh Frozen Plasma.* Fresh Frozen Plasma shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and minimal manipulation of the donor's tissue. The plasma shall be separated from the red blood cells, frozen solid within 6 hours after phlebotomy, and stored at −18 °C or colder.

(c) *Liquid Plasma.* Liquid Plasma shall be separated from the red blood cells within 26 days after phlebotomy (within 40 days after phlebotomy when CPDA–1 solution is used as the anticoagulant) and shall be stored at a temperature of 1 to 6 °C within 4 hours after filling the final container.

(d) *Platelet Rich Plasma.* Platelet Rich Plasma shall be prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and manipulation of the donor's tissue. The plasma shall be separated from the red blood cells by centrifugation within 4 hours after phlebotomy. The time and speed of centrifugation shall have been shown to produce a product with at least 250,000 platelets per microliter. The plasma shall be stored at a temperature between 20 to 24 °C or between 1 and 6 °C, immediately after filling the final container. A gentle and continuous agitation of the product shall be maintained throughout the storage period, if stored at a temperature of 20 to 24 °C.

(e) *Modifications of Plasma.* It is possible to separate Platelets and/or Cryoprecipitated AHF from Plasma. When these components are to be separated, the plasma shall be collected as described in § 640.32 for Plasma.

(1) Platelets shall be separated as prescribed in subpart C of part 640, prior to freezing the plasma. The remaining plasma may be labeled as Fresh Frozen Plasma, if frozen solid within 6 hours after phlebotomy.